

REMARKS

Claims 33-59 were pending. Claims 37, 38, 45, 46, 53, and 54 have been canceled without prejudice. Claims 33, 50, and 59 have been amended.

Specifically, claims 33, 50, and 59 have been amended to incorporate the subject matter of claim 46, *i.e.*, to specify that the antigen is β hCG, Gp100, prostate associated antigen, or Pmel-17. Claims 33, 50, and 59 have further been amended to specify the NY-ESO-1 and HIV antigens. Support for these amendments can be found throughout the application as originally filed, *e.g.*, page 16, lines 6-28.

The foregoing claim amendments should in no way be construed as acquiescence to any of the Examiner's rejections and were made solely to expedite prosecution of the application. Applicants reserve the right to pursue claims to the canceled subject matter, or any subject matter which they are entitled to claim, in this or a separate application. No new matter has been added.

Rejection of Claims 33-37, 39-45, and 47-59 Under 35 U.S.C. §102(b)

Claims 33-37, 39-45, and 47-59 are rejected as being anticipated by WO 01/85798. Applicants respectfully traverse this rejection based on the previous reasons of record. However, to expedite prosecution, independent claims 33, 50, and 59 have been amended to incorporate the subject matter of claim 46, which is not subject to this rejection. Accordingly, this rejection is moot.

Rejection of Claims 33, 38 and 46 Under 35 U.S.C. §103(a)

Claims 33, 38 and 46 are rejected as being unpatentable over WO 01/85798 in view of US 5,869,057. The Examiner acknowledges that WO 01/85798 "does not teach the use of β hCG as an antigen." However, the Examiner relies on US 5,869,057 as teaching "the use of β hCG as an antigen . . . as well as its capacity to present antigen to CD4+ cells."

Applicants respectfully traverse this rejection. As amended, the claimed methods for generating a CTL response employ conjugates which include anti-MMR antibodies and particular antigens, namely β hCG, Gp100, prostate associated antigen, and Pmel-17, which are not described in the primary reference. Moreover, as required by the USPTO Examination Guidelines for Determining Obviousness (Fed. Reg. Vol. 72, No. 195 (October 10, 2007)), the Examiner has failed to establish at least "a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable." Indeed, as described in

detail in Applicants' previous responses, the references cited by the Examiner fail to provide evidence that the claimed CTL response could predictably be generated, let alone which particular types of antibodies can be used as targeting agents, which receptors to target, or which antigens can be targeted. In fact, the '057 patent fails to teach or suggest using any type of antibody and states that its invention provides advantages over the prior art (which includes the use of antibody technology). In particular, the '057 patent teaches linking (via recombinant DNA technology) a microbial (non-self) gene product (*e.g.*, a prokaryotic helper T cell epitope, such as heat-labile enterotoxin B subunit (LTB)) to a "self" gene product (*e.g.*, a β hCG epitope) for the production of an immune response to the self protein. The '057 patent fails to teach or suggest using any type of antibody and states that its invention provides advantages over the prior art (which includes the use of antibody technology). For example, the '057 patent states (at col. 11, ll. 63) that:

[the] invention offers four primary advantages over prior art. First, recombinant DNA technology enables consistent production of a defined vaccine formulation. This is superior to peptide synthesis and chemical conjugation, which lead inevitably to variability in preparation that can affect vaccine potency. Second, due to the natural action of microbial products, my invention precludes the need for additional adjuvants such as muramyl dipeptide in the final vaccine formulation. Third, recombinant protein expression enables lower costs of vaccine manufacture relative to the significant expense of peptide synthesis and chemical conjugation. Finally, recombinant expression of self proteins in a form linked to microbial products may facilitate the introduction of such formulations via mucosal immunization. This could feasibly include oral, nasal, or rectal administration and is not possible with the chemical conjugates described above.

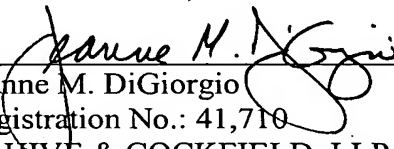
Based on at least the foregoing, the cited references, either alone or in combination, fail to teach or suggest forming a conjugate of β hCG and an anti-human MRR antibody since these references are either silent about the elements of the claimed conjugate or teach away from the use of antibody conjugates in general. Indeed, the '057 patent teaches away from using any type of antibody, let alone the particularly claimed antibody encompassed by the claimed methods, thereby, demonstrating the lack of motivation and/or predictability that existed in the art for arriving at the claimed invention. Accordingly, a *prima facie* case of obviousness has not been made.

SUMMARY

Based on the foregoing amendments and arguments, reconsideration and withdrawal of all the rejections and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

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Respectfully submitted,

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